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| EXAMINER |
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PAPER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/811,277
Filing Date: March 25, 2004
Appellant(s): ZHONG ET AL.

**MAILED
FEB 07 2008
GROUP 1700**

Glenn M. Seager
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 3, 2007 appealing from the Office action mailed December 29, 2006.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

| | | |
|-----------|-------------------|--------|
| 6,024,722 | RAU et al. | 2-2000 |
| 3,388,095 | HUNTJENS | 6-1968 |
| 5,514,379 | WIESSLEDER et al. | 5-1996 |
| 6,517,570 | LAU et al. | 2-2003 |

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(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections – 35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 5 - 17, 19 - 42 and 51 - 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al (U.S. Patent No. 6,024,722) in view of Huntjens (U.S. Patent No. 3,388,095).

With regard to Claims 3 and 6, Rau et al disclose a medical device (catheter; column 3, line 59) comprising an elongate flexible element (shaft; column 3, line 60) made from a first polymer (column 9, lines 63 - 65) comprising phenylene units (column 9, line 66) that is thermoplastic (undergoing melt flow; column 10, line 12). Rau et al fail to disclose a polymer comprising substituted 1,4 polyphenylene. Huntjens disclose a polymer with phenylene units comprising substituted 1,4 polyphenylene in the making of articles (column 2, lines 14 - 19) for the purpose of obtaining articles having unique physical properties over a broad temperature range (column 1, line 25). One of ordinary skill in the art would therefore have recognized the advantage of providing for the substituted 1,4 polyphenylene of Huntjens in Rau et al, which comprises a catheter, therefore an article, depending on the desired physical properties of the end product. It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a polymer comprising substituted 1,4

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polyphenylene in Rau et al in order to obtain articles having unique physical properties over a broad temperature range as taught by Huntjens.

With regard to Claim 5, Rau et al fail to disclose a polymer comprising benzoyl substituted 1,4 phenylene units. However, Rau et al disclose a polymer comprising phenylene units (column 9, line 66). It would therefore have been obvious for one of ordinary skill in the art to have selected benzoyl substituted 1,4 phenylene units, as benzoyl substituted 1,4 phenylene units are among the known phenylene units.

With regard to Claims 7 - 9, the medical device is an intravascular guidewire (column 4, lines 14 - 15), therefore a core wire, which is intravascular (used in angioplasty; column 2, line 22); the core wire therefore extends from a position proximate the proximal end of the guidewire to a position proximate the distal end of the guidewire.

With regard to Claim 10, the core wire comprises a plurality of elongate longitudinally extending threads made from the polymer (parallel aligned filaments; column 9, line 5).

With regard to Claims 11 - 13, 17 - 18, 25 -26 and 38, Rau et al fail to disclose a core wire having a circular cross sectional shape and rectangular cross sectional shape and cruciate cross sectional shape and a sleeve which is a coil and a wound flat tape and a distal varying thickness to create a first region having a first compliance and a second region having a second compliance less than the first compliance. However, Rau et al disclose a wire, therefore having an elongate shape, and a sleeve and layer, therefore having a uniform thickness. It would have been an obvious matter of design choice to have provided a circular or rectangular or cruciate cross sectional shape of the core wire and sleeve having a coil shape and a flat tape shape and distal varying thickness of the layer of Rau et al, since such a modification would have involved

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a mere change in shape. A change in shape is generally recognized as being within the level of ordinary skill in the art.

With regard to Claim 14, the flexible element is a sleeve extending over the wire (column 4, lines 12 - 15; Figure 1).

With regard to Claim 15, Rau et al disclose a second sleeve, disposed on the first, made from the polymer (outer layers; column 10, line 20).

With regard to Claim 16, the sleeve is an extruded tube (column 5, line 47).

With regard to Claims 19 - 24 and 27 - 28, the sleeve disclosed by Rau et al is a mesh and a weave (satin weave; column 9, line 3).

With regard to Claim 29, Rau et al disclose an inner sleeve and an outer sleeve, the flexible elongate member comprising a plurality of elongate threads disposed between the inner sleeve and the outer sleeve (the elongate member comprises a weave comprising yarn having polymeric material on its inner and outer surfaces; column 9, lines 10 - 15).

With regard to Claims 30 - 31, Rau et al disclose a blend of the first polymer and a second polymer (blend layer; column 9, line 59).

With regard to Claims 32 - 35, the medical device disclosed by Rau et al comprises a balloon (column 3, lines 60 - 66), therefore balloon sleeve.

With regard to Claims 36 - 37 and 39, the sleeves disclosed by Rau et al are extruded by any extruder (column 3, lines 55 - 57), therefore including coextrusion of the first polymer in a first layer and the second polymer in a second layer.

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With regard to Claims 40 and 51, Rau et al disclose that the medical device, comprising a crosslinkable polymer, is known in the art (thermoset polyimide; column 1, line 43); Rau et al therefore disclose a second polymer which is crosslinked or is not crosslinked.

With regard to Claims 41 - 42, the balloon disclosed by Rau et al has a thickness of 1 mil (0.001 inches; column 5, lines 48 - 50).

With regard to Claim 52, the first polymer disclosed by Rau et al is a rigid rod polymer as discussed above, and is extruded as discussed above, and is therefore cooled from an extrusion process; Rau et al therefore disclose a first polymer that is crosslinked. However, the claimed aspect of the device being formed by providing the first and second polymer, followed by coextruding, followed by crosslinking the first and second polymer, is given little patentable weight as it is directed to process limitation rather than a structural limitation.

Claims 45 - 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al (U.S. Patent No. 6,024,722) in view of in view of Huntjens (U.S. Patent No. 3,388,095) and further in view of Weissleder et al (U.S. Patent No. 5,514,379).

Rau et al and Huntjens disclose a medical device comprising a catheter as discussed above. With regard to Claims 45 - 50, Rau et al and Huntjens fail to disclose a catheter comprising a hydrogel coating and a therapeutic agent and a paramagnetic material comprising gadolinium III and a lubricious sheath disposed around the elongate member comprising a hydrogel polymer.

Weissleder et al teach a catheter comprising a lubricious coating (column 10, lines 35 - 40), therefore a sheath comprising a hydrogel comprising gadolinium III (column 4, lines 1 - 8)

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for the purpose of using a coating that is biocompatible and biodegradable (column 11 lines 10 - 14). one of ordinary skill in the art would therefore have recognized the advantage of providing for the coating of Weissleder et al in Rau et al and Huntjens, which comprises a catheter, depending on the desired biocompatibility and biodegradability of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a hydrogel coating and a therapeutic agent and a paramagnetic material comprising gadolinium HI and a lubricious sheath disposed around the elongate member comprising a hydrogel polymer in Rau et al and Huntjens in order to obtain a coating that is biocompatible and biodegradable as taught by Weissleder et al.

Claims 43 - 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al (U.S. Patent No. 6,024,722) in view of Huntjens (U.S. Patent No. 3,388,095) and further in view of Lau et al (U.S. Patent No. 6,517,570 B1).

Rau et al and Huntjens disclose a medical device comprising a rigid rod polymer as discussed above. With regard to Claims 43 - 44, Rau et al and Huntjens fail to disclose a device comprising a self- expanding stent comprising a plurality of struts.

Lau et al teach a rigid rod polymer (column 13, line 5) in the making of a self- expanding stent comprising a plurality of struts for the purpose of obtaining a stent that does not shorten upon delivery (column 2, lines 13 - 30). One of ordinary skill in the art would therefore have recognized the advantage of providing for the device of Lau et al in Rau et al and Huntjens, which comprises a rigid rod polymer, depending on the desired shortening of the end product.

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It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a device comprising a self- expanding stent comprising a plurality of struts in Rau et al and Huntjens in order to obtain a stent that does not shorten upon delivery as taught by Lau et al.

(10) Response to Argument

Appellant argues that Huntjens does not teach a polymer having a liquid crystal structure as required by Rau et al.

However, Huntjens is cited only for the teaching that it would have been obvious for one of ordinary skill in the art to have provided for a substituted poly 1,4 phenylene as the phenylene of Rau et al; furthermore, Huntjens is not limited to a non – liquid crystal poly 1,4 phenylene.

Appellant also argues that Huntjens is directed to stabilization, and is not in Appellant's field of endeavor.

However, in view of Huntjens it would have been obvious for one of ordinary skill in the art to have provided for a poly 1,4 phenylene as the phenylene of Rau et al; furthermore, stabilized polymers are not excluded by Rau et al, which is in the field of medical devices and therefore is in Appellant's field of endeavor.

Appellant also argues that the advantages taught by Huntjens, unique physical properties over a broad temperature range, are little more than puffery.

However, there is no evidence provided that the advantages taught by Huntjens are exaggerated, and therefore constitute puffery.

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Appellant also argues that if the polymer of Huntjens possesses unique properties, the polymer of Huntjens cannot possess the properties of the polymers disclosed by Rau et al.

However, the polymer of Huntjens is not excluded by the range of polymers disclosed by Rau et al, because Rau et al discloses polymers comprising phenylene and Huntjens teaches one species of polymer that comprises phenylene.

Appellant also argues that the teaching of use of the properties over a broad temperature range is of little interest to one making a catheter of Rau et al because the catheter will only be exposed to a narrow temperature range in body vessel lumens.

However, if the advantageous properties possessed by the polymer of Rau et al are possessed over a broad temperature range with regard to physical polymer properties, it is clear that the properties will be possessed at the temperature of body vessel lumens.

Appellant also argues that benzoyl is but one functional group among many phenylene functional groups; one of ordinary skill in the art, Appellant argues, would therefore not have provided for benzoyl as the functional group of Rau et al.

However, because benzoyl is a known functional group among the functional groups of phenylene, one of ordinary skill in the art would have recognized at the time Appellant's invention was made that benzoyl is included within the disclosure of phenylene by Rau et al.

Appellant also argues that Rau et al fail to disclose a thermoset polyimide; Rau et al, Appellant argues, disclose a polyimide that is thermoplastic, and disclose that the thermoset polyimides that have previously been the material of choice for catheters is not meltable.

However, because Rau et al disclose the use of thermoset polyimide in catheters that have been previously used and that the disclosed thermoplastic polyimides are a meltable alternative

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to those previously used, Rau et al disclose that thermoset polyimides are known in the art and therefore read on the claimed invention of a medical device comprising a polymer that is crosslinked.

Appellant also argues that it is a contradiction to state that Rau et al disclose a polymer that is crosslinked or not crosslinked.

However, because Rau et al disclose thermoset polyimide and thermoplastic polyimide as alternatives in the making of a catheter, Rau et al alternatively disclose the use of a crosslinked or non – crosslinked polymer in the making of a catheter.

Appellant also argues that structural limitations regarding crosslinking of the claimed polymer have not been addressed.

However, as stated above; the use of a crosslinked polymer is disclosed by Rau et al; structural limitations regarding crosslinking of the claimed polymer have therefore been addressed.

Appellant also argues that Weissleder et al and Lau et al fail to provide requisite motivation to establish obviousness.

However, no reasons are stated by Appellant as to why requisite motivation has not been provided.


(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

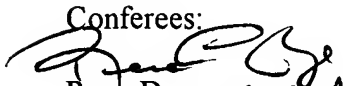
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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,


Marc A. Patterson

Conferees:


Rena Dye


Romulo Delmendo